

इंटरनेट

मानक

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“जानने का अधिकार, जीने का अधिकार”

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“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”

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“Step Out From the Old to the New”

IS 11163 (1985): Specification for First-Aid Dressings [MHD
19: Immuno-Biological Diagnostic Kits]



“ज्ञान से एक नये भारत का निर्माण”

Satyanarayan Gangaram Pitroda

“Invent a New India Using Knowledge”



“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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AMENDMENT NO. 1 MAY 1991
TO
IS 11163 : 1985 SPECIFICATION FOR
FIRST-AID DRESSINGS

(Page 1, Table 1) — Substitute the following for the existing table:

TABLE 1 MANUFACTURING PARTICULARS OF BASIC FABRIC

(Clause 3.1.1)

Particulars	Requirements	Method of Test, Ref. to IS:
Ends per dm, <i>Min</i>	250 } 230 }	IS : 1963-1981 'Methods for determination of threads per unit length in woven fabrics (<i>second revision</i>)'
Picks per dm, <i>Min</i>		
Weight, g/m ² , <i>Min</i>	115	IS : 1964-1970 'Methods for determination of weight per square metre and weight per linear metre of fabrics (<i>first revision</i>)'

(Page 2, clause 5.4, line 2) — Substitute 'self-adhesive plaster' for 'self-adhesiveness, plaster'.

[Page 2, clause 7(b)] — Substitute 'pad' for 'paid'.

[Page 2, clause 7(h)] — Substitute 'label' for 'lable'.

(MHD 15)

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Indian Standard

SPECIFICATION FOR FIRST-AID DRESSINGS

1. Scope — Specifies the requirements of first-aid dressings.

2. Description — A first-aid dressing consists of an absorbent pad covered with an antistick material fixed to a self-adhesive plaster. The pad and the adhesive margin are covered with a suitable protector. The pad may be coloured, if necessary, with a suitable non-toxic dye and/or medicated with any permitted antiseptic. The dressings may be sterilized or medicated. The self-adhesive plaster can be film or fabric based. If it is film based, it should be perforated throughout and if fabric based, it may be perforated and the edges shall not show fray.

3. Material

3.1 Fabric — The fabric shall be plain woven and made from cotton or rayon or a blend of cotton and rayon.

3.1.1 The fabric shall be reasonably free from spinning, weaving and processing defects. It shall be finished to a good white colour or dyed to any suitable colour with a non-toxic dye. The basic fabric shall conform to the particulars given in Table 1.

TABLE 1 MANUFACTURING PARTICULARS OF BASIC FABRIC

Particulars	Requirements	Method of Test Ref. to IS :
Ends per dm <i>Min</i>	250	IS : 1963-1969 'Methods of determination of threads per unit length in woven fabrics (first revision)'
Picks per dm <i>Min</i>	230	
Weight g/m ² <i>Min</i>	115	

3.2 Film — The requirements for the film should be as agreed to between the manufacturer and the supplier.

4. Requirements

4.1 Description — The dressing shall be circular, square or rectangular in shape.

4.1.1 The pad shall be fixed as centrally as possible to a self-adhesive dressing.

4.1.2 The width of the adhesive margin shall be not less than 10 percent of the overall dimensions of the dressing. The width of the adhesive margin on any one side shall be not less than half of the adhesive margin on the opposite side.

4.1.3 The pad and the margin of adhesive surface shall be covered by a suitable protector. The pad shall not get detached from the plaster when the protector is removed.

4.2 Dimensions

4.2.1 The dimensions of the dressing shall be as agreed to between the purchaser and the manufacturer.

4.2.2 The length shall not be less than 98 percent of the stated length. The width shall not be less than 95 percent of the stated width.

4.3 Self-Adhesive Plaster — Self-adhesive plaster shall be applied evenly with a pressure sensitive adhesive mass which shall not off-set while removing the protector. The adhesive mass may be made porous or permeable to air.

4.4 Sterilization — The dressing may be sterilized or medicated. It may be sterilized by any suitable sterilization process in accordance with IS : 10150 - 1981 'Guide for sterilization of medical products'. The sterility shall be tested as specified in British Pharmaceutical Codex 1973, Appendix 28, Page 917.

Adopted 18 January 1985

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4.5 Pad (With or Without Medication) — The pad is a piece of suitable absorbent material. It may be dyed and/or medicated with suitable medicants. If it is medicated, the medication shall be as uniform as possible and the content of medication shall be between 70 to 130 percent of that claimed on the label.

5. Sampling and Criteria for Conformity for First-Aid Dressings

5.1 In any consignment all the first-aid dressings produced under similar conditions from the same raw material and of the same dimension shall constitute a lot.

5.2 The number of dressings to be selected from each lot shall depend upon the size of the lot and shall be in accordance with columns 1 and 2 of Table 2 :

TABLE 2 NUMBER OF DRESSING TO BE SELECTED FOR SAMPLING

Lot Size <i>N</i> (1)	Sample Size <i>n</i> (2)	Acceptance Number (3)
Up to 300	13	1
301 to 500	13	1
501 to 1 000	20	2
1 001 to 3 000	32	3
3 001 to 10 000	32	3
10 001 and above	50	5

5.2.1 These dressings shall be selected from the lot at random and in order to ensure the randomness of selection, procedures given in IS : 4905 - 1968 ' Methods for random sampling may be followed. '

5.3 Number of Tests and Criteria for Conformity — The number of dressings selected at random in accordance with col 1 and 2 of Table 2 shall be tested for general requirements (4.1) and dimensions (4.2). The lot shall be considered as conforming to these requirements if the number of defectives found in the sample is less than or equal to the corresponding acceptance number of defectives as given in col 3 of Table 2.

5.4 If the lot is conforming to the requirements as mentioned in 5.3, the test for fabric (3.1), self-adhesiveness, plaster (4.3), sterilization (4.4), and, pad (4.5) shall be carried out. All the dressings in the sample shall be divided into four more or less equal parts and the dressings in each sub-sample shall be tested for the above mentioned test. The lot shall be considered as conforming to the respective requirement if none of the dressings in each sub-sample fails in that particular requirement.

5.5 The lot shall be considered as conforming to the standard if 5.3 and 5.4 are satisfied.

6. Packaging — If sterilized, the packing must be adequate to maintain the sterility of the dressing.

7. Marking — Each pack shall be marked with the following information:

- Generic name and the trade name, if any, of the product;
- The name of the dye or colour, if used on the pad, should be stated on the label;
- Manufacturing Licence No. and registered address of the manufacturer;
- Dimensions and quantity of dressings;
- Batch No.;
- Month and year of manufacture;
- The name and proportion of the medicament, if present; and
- If sterilized, it should be stated so on the label.

7.1 ISI Certification Marking — Details available with the Indian Standards Institution.

EXPLANATORY NOTE

First-aid dressing is used as an aid to protect the injured part from infection, when immediate medical attention is not available.